

REMARKS

Claims 170-181 are pending. In the instant Office Action the Examiner alleges that the pending claims lack a special technical feature over US2003/00554337 (Birkett publication), and thus are subjected to a restriction and/or election requirement. The claim groups are as follows:

I. Claims 170-181 drawn to methods for producing an immune response through administration of a composition comprising a hybrid hepadnavirus core protein;

II. Claims 170-181 drawn to methods for producing an immune response through administration of a composition comprising an expression vector encoding a hybrid hepadnavirus core protein;

III. Claims 170-181 drawn to methods for producing an immune response through administration of a composition comprising a hybrid hepadnavirus core protein, and an expression vector encoding the core protein.

In addition, the Examiner alleges that the pending claims are directed to more than one species of generic invention, and thus are also subjected to a species election requirement. The hepadnavirus core antigen species are as follows:

- (a) a rodent hepadnavirus (Claims 170-174);
- (b) an avihepadnavirus (Claims 170-173 and 175);
- (c) a human hepatitis B virus (Claims 176-180); and
- (d) a nonhuman primate hepadnavirus (Claims 176-179 and 181).

Applicants hereby elect Group I, *with traverse*, with rodent hepadnavirus core antigens as the species for initial examination purposes. In particular, Applicants hereby amend Claims 170 and 174-176, cancel Claims 173 and 179-181, and introduce new Claims 188-197, in order to

further their business interests, without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar or broader claims in one or more future application(s). In particular, Applicants have amended independent Claim 170 to recite "a hybrid particle comprising a polypeptide comprising a non-primate hepadnavirus core antigen," and independent Claim 176 to recite "a hybrid particle comprising a polypeptide comprising a nonhuman primate hepadnavirus core antigen." Both independent claims have also been amended to recite *one of* a hybrid particle, and an expression vector. Support for these amendments can be found throughout the application as filed, such as in the legend of Figures 14 and 15, which depict the immunogenicity of exemplary hybrid particles. Support for the "nonhuman primate" limitation can be found in original Claim 181, now canceled. In addition, support for new Claims 188 and 189 can be found but is not limited to Example 16, which teaches the solution to the "problem of pre-existing anti-HBc antibodies is to use a carrier platform, which will not be recognized by natural anti-HBc antibodies" (Specification, at page 132, lines 11-13). Moreover, support for new Claims 190-195 can be found but is not limited to original Claims 111-130 and 149-157 (now canceled) directed to various non-primate and nonhuman primate hepadnavirus core antigens. Lastly, support for new Claims 196 and 197 can be found but is not limited to original Claims 23-27, 42-48, 58, 59, 93, 94, 101 and 102 (now canceled) directed to hepadnavirus artificial C- termini. Thus the amendments and new claims do not introduce new matter.

In contrast to the amended claims, the Birkett publication does not teach how to produce polypeptides comprising a heterologous antigen and a non-primate or nonhuman primate hepadnavirus core or expression vector encoding said polypeptide, let alone polypeptides that can assemble as hybrid particles. In addition, Birkett does not teach that hybrid particles based on non-primate or nonhuman primate hepadnavirus cores are suitable for use in producing an immune response, let alone an immune response in human hepatitis B virus-exposed human subjects. As such Applicants contend that the amended claim set is linked to form a single general inventive concept as required by PCT Rule 13.1 in view of the Birkett publication, and thus the restriction between claim Groups I and II should be withdrawn. Applicants note that the amendments to the claims have eliminated claim Group III. Even so Applicants submit that pending Claims 170-172,

174-178, 188-197 read upon Group I, and that pending Claims 170-172, 174, 190-193, 196 and 197 read upon rodent hepadnavirus cores. Applicants respectfully reserve their right to consideration of claims reading upon additional species of hepadnavirus cores in the event that claims reading upon rodent hepadnavirus cores are found to be allowable.

CONCLUSION

Applicants believe that the amended claims are in condition for allowance. However should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing Attorney Docket No. **643662000200**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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